

**DEPARTMENT OF CONSUMER AFFAIRS  
ACUPUNCTURE BOARD**

**INITIAL STATEMENT OF REASONS**

**Hearing Date:** August 22, 2005

**Subject Matter of Proposed Regulations:** Single Use Needles

**Sections Affected:** 1399.450, 1399.451, and 1399.454

**Specific Purpose of each adoption, amendment, or repeal:**

Requiring single use needles is a protective measure to prevent the transmission of infections and diseases. Given life-threatening contagious diseases, such as human immune deficiency disease, hepatitis, and antibiotic-resistant bacteria, the Board must promote basic public health measures of infection control such as requiring the use of disposable needles.

**Factual Basis/Rationale**

In 1996, the U.S. Food and Drug Administration (FDA) classified acupuncture needles as medical, class II, devices under FDA regulations (21 CFR 880.5580). As with other class II devices, the needles are required to have proper labeling. The labeling must include a statement “for single use only”.

The 1997 National Institutes of Health Consensus Statement on Acupuncture reported that “Use of acupuncture needles should always follow FDA regulations, including use of sterile, single-use needles. It is noted that these practices are already being done by many acupuncture practitioners; however, these practices should be uniform.”

A report issued by the National Center for Complimentary and Alternative Medicine (NCCAM) indicated that complications have resulted from inadequate sterilization of needles. The NCCAM recommended that practitioners should use a new set of disposable needles taken from a sealed package for each patient.

In September 2004, the Little Hoover Commission issued a report on the “Regulation of Acupuncture, A Complementary Therapy Framework”, which also identified the issue of single-use needles. Their report stated that federal recommendations for improving patient safety – for instance, the exclusive use of single-use needles – be quickly adopted.

The issue of single-use needles was also addressed in the 2004-05 Sunset Review Process with the Joint Committee on Boards, Commissions and Consumer Protection. The Joint Committee supported the Little Hoover Commission's findings and also recommended the issue of single-use needles be immediately promulgated as emergency regulations

With new stronger strains of diseases and infections surfacing that are resistant to antibiotics, the Board cannot place patients at risk by continuing to allow the older practice of sterilizing needles between uses. Just one instance of improper sterilization of a needle could place a patient at a severe health risk.

An Occupational Analysis, which was conducted in 1996, included a survey which was sent to licensed acupuncturists. The survey included a question on type of needle used (disposable vs. reusable). Ninety nine percent (99%) of those responding indicated they used disposable needles only. While there is a high percentage of reported compliance, the Board feels that one percent is a significant number when we are referring to patient safety.

### **Underlying Data**

FDA Regulations 21 CFR 880.5580; 1997 National Institutes of Health Consensus Statement on Acupuncture; National Center for Complimentary and Alternative Medicine report; Little Hoover Commission Report, September 2004; and 1996 Occupational Analysis.

### **Business Impact**

An Occupational Analysis was conducted in 1996 which included a survey that was sent to 1,070 licensed acupuncturists. The survey included a question on the type of needles acupuncturists use (disposable vs. reusable) in their practices. Ninety nine percent (99%) of those who responded to the survey answered that they only use disposable needles. While this survey supports a finding that there is a high percentage of acupuncturist that are using single use needles, the Board acknowledges that the proposed regulatory action may have a direct economic or fiscal impact on those acupuncturists who are still sterilizing their needles. However, the overall fiscal impact would be minimal because the average needle only costs between a half cent to three cents. In fact, the switch to the use of single use needles may provide a cost savings for licensees who are currently sterilizing needles because it would eliminate the cost of purchasing and maintaining equipment as well as the labor costs involved in the sterilization process.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.